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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,596	07/27/2007	Ellen D Jorgensen	VT0B.302NP	9085

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EXAMINER

POHNERT, STEVEN C

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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06/12/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/593,596	Applicant(s) JORGENSEN ET AL.	
	Examiner STEVEN C. POHNERT	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-20, drawn to method of making a tobacco product. (subject to further restriction)

Group 2, claim(s) 22, drawn to a tobacco product.

Group 3, claim(s) 23-46, drawn to a method of reducing the potential of a tobacco consumer to acquire a tobacco related disease. (subject to further restriction)

Group 4, claim(s) 47-51, drawn to method to identify a gene modulated by exposure to tobacco smoke.

Group 5, claim(s) 52, drawn to method to identify a predilection to acquire tobacco related disease. (subject to further restriction)

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Bosio et al (Carcinogenesis (2002) Volume 23, pages 741-748) in view of Conkling et al (US Patent 6,423,520 Issued July 23, 2002).

Bosio et al teach a method of screening gene the effects of smoke bubbled PBS on gene expression of Swiss albino 3T3 fibroblast by microarray technology (see abstract, page 742, 1st column, cell culture). Bosio teaches the genes recited in Table 1 genes that have a greater than 4 fold induction or repression of expression. Bosio et al further teaches a time course to exposure of the cells to the smoke, thus teaching first and second populations of cells (see figure 2). Bosio further teaches an array of 537 stress induced gene that comprise those recited in claim 18. Bosio et al further teaches this method for the identification of the underlying mechanism by which cigarette smoke promotes cancer, chronic obstructive pulmonary disease, and

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cardiovascular disorder (see page 741, 1st paragraph of text).

Bosio et al does not teach the making of tobacco products or cigarettes based on the differential regulation of gene expression by different products.

However, Conkling et al teaches a method of producing tobacco plants with reduced nicotine levels, given the addictive nature of nicotine (see column 1, lines 28-31). Conkling et al teaches nicotine expression is regulated by quinolate phosphoribosyl transferase and putrescene methyl transferase (see column 3, lines 51-61). Conkling et al further teaches reduction of nicotine content of a tobacco by targeting the rate limiting steps of the nicotine production pathway by antisense technology (see column 1, lines 44-55 and figures 5 and 6). Conkling further teaches production of cigars and cigarettes from the tobacco of genetically altered plants (see column 4, lines 45-50).

Therefore it would have been obvious to one of ordinary skill in the art to use the method of screening the transcriptional effects of tobacco smoke of Bosio and method of producing tobacco with reduced nicotine as taught by Conkling. The skilled artisan would be motivated to combine the teaching of Bosio and Conkling to produce a tobacco product that is less addictive resulting in lower risk of cancer, chronic obstructive pulmonary disease, and cardiovascular disorder. The combined teaching of Bosio and Conkling would result in a method of screening different species and transgenic tobacco for altered transcriptional responses and thus identification of tobacco with less adverse affects.

Thus the claims lack a special technical feature over the prior art.

Further Restriction

2. Additionally, groups 1, 3 or 5 named above are subject to further restriction.

Applicant must further select a specific first gene and specific second gene if groups 1 or 3 are elected. Applicant must further elect a specific gene or combination of genes if group 5 is elected. The nucleic acid sequences of are directed to different genes and sequences within a gene and thus have no significant structural element that can be readily ascertained and thus no special technical feature can be determined.

Lack of unity exists between all of the various combinations as each gene. The combination of genes do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: the description fails to disclose that all of the genes share a common structure or function.

Further ISPE Guidelines Jan 2004 states:

10.07 If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. ... Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and satisfies the requirement of unity of invention and the combination claim includes all the features of the subcombination.

10.08 If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN C. POHNERT whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/
Examiner, Art Unit 1634
Steven Pohnert